Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 204031
Company: MALLINCKRODT INC

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204031s004s005lbl.pdf#page=34)

Products on NDA 204031

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
XARTEMIS XR	ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE	325MG;7.5MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 204031

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
03/11/2014	ORIG-1	Approval	Type 3 - New Dosage Form	PRIORITY	**Label (PDF) (https Letter (PDF) (https Review (https://ww**

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
09/18/2018	SUPPL-5	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
09/18/2018	SUPPL-4	REMS - PROPOSAL - D-N-A	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
12/16/2016	SUPPL-3	Labeling-Package Insert, Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**
03/12/2015	SUPPL-1	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc**

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
01/26/2015	SUPPL-2	Manufacturing (CMC)	

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Labels for NDA 204031